



MJ821n

VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-99-80

July 27, 1999

Wilman D. Iturralde
President, Polar Seafood Corporation
4862 N.W. 5th Street
Miami, Florida 33126

Dear Mr. Iturralde:

On January 6 & 7, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility located at 4862 N.W. 5th Street, Miami, Florida 33126. Investigator Maria A. Medina documented for the second consecutive time, serious deviations from the HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). The existence of these deviations causes the fish products being imported and distributed by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The following deficiencies were noted:

Importer Deviations:

- Failure to adequately perform the affirmative step in 21 CFR 123.12(a)(2)(ii)(D) by not maintaining a copy of the foreign processor's written guarantee;
- Failure to have and implement written product specifications that list all appropriate safety hazards, [21 CFR 123.12(a)(2)(i)];

Foreign Processor Deviations:

- Failure to identify each hazard associated with fresh fish (i.e., Mahi-Mahi/scombrototoxin formation), [21 CFR 123.6(c)(1)];

Mr. Wilman D. Iturralde

Page 2

July 27, 1999

- Failure to identify the packing step as a critical control point in the HACCP plan for fresh Mahi-Mahi, [21 CFR 123.6(c)(2)];
- Failure to have adequate monitoring procedures in the written plan for fresh Mahi-Mahi, [21 CFR 123.6(c)(4)], in that the plan does not include the use of thermometers to monitor temperature;
- Failure to identify an appropriate critical limit in the written HACCP plan at the processing step CCP, as it does not indicate the maximum processing temperature, [21 CFR 123.6(c)(3)];
- Failure to provide the appropriate corrective action, [21 CFR 123.7(a)(1) and (b)], in the HACCP plan for the processing step when the critical limits (i.e., temperature/time) have been exceeded. The corrective action fails to ensure that unsafe product does not reach the consumer, and does not correct the problem that caused the critical limit deviation.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these and all violations at your firm. Failure to achieve corrective action may result in regulatory action without further notice. These actions may include seizure or injunction under the Federal Food, Drug, and Cosmetic Act. In addition, until these deficiencies are corrected, the Agency may not issue any export certificates for shipments and may detain your imported seafood products without examination.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections

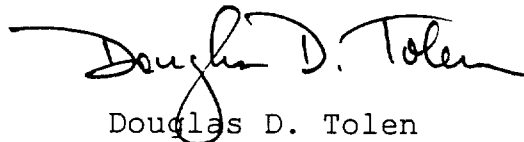
Mr. Wilman D. Iturralde
Page 3
July 27, 1999

cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

In addition, your firm has failed to list and implement written verification procedures and the foreign processor's HACCP plan is not species specific or signed and dated and fails to include calibration of the thermometers as an ongoing verification procedure.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is fluid and cursive, with a long horizontal line extending from the start of the name.

Douglas D. Tolen
Director, Florida District